UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL NO. 1456
THIS DOCUMENT RELATES TO: TRACK TWO SETTLEMENT	CIVIL ACTION: 01-CV-12257-PBS Judge Patti B. Saris

PLAINTIFFS' SECOND SUPPLEMENTAL SUBMISSION IN SUPPORT OF A REBALANCED TRACK TWO SETTLEMENT

[FILED UNDER SEAL]

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

CASES

I. INTRODUCTION

At the Track Two settlement fairness hearing held August 8, 2011, the Court requested that Plaintiffs make a supplemental filing that provides a closer examination of spreads for nine of the 22 brand name drugs included in Group B, determine whether any of those spreads are "significantly and consistently over 40 percent" and report on whether any of those drugs should be moved to Group A. Dr. Hartman has augmented his analysis of all 22 brand name drugs in Group B, including the nine referenced by the Court. Based on additional data supplied by the Track Two Defendants, Dr. Hartman has concluded that none of the spreads for any of the 22 drugs, let alone the nine discussed at the hearing, are "significantly and consistently over 40 percent." Thus, in this submission, Plaintiffs recommend that all 22 of the brand name drugs remain in Group B.

This submission also reports on the projected impact of making the following changes to the distribution model: (i) Epogen becomes a Group B drug, subject to each claimant demonstrating that he or she was administered Epogen and not Procrit for non-dialysis use; (ii) Group A overcharges are doubled only for the Heartland Period ending December 31, 2003; and (iii) each Eligard claimant must demonstrate that he or she was administered Eligard instead of Lupron, with which Eligard shares a J-Code. These changes result in an increase in the estimated pro rata co-pay recovery for the Group B drugs to just under 15 percent. This provides a substantial recovery to Group B claimants given that the co-pay itself is much greater than actual damages (which are but a percentage of the co-pay).

The modified reallocation and redistribution plan accomplishes the following:

1. Class 1 and 3 consumers receive ***double*** their actual damages incurred on eligible administrations of Group A drugs for administrations during the Court's "Heartland Period."

2. Class 3 consumers electing the "Easy Pay" refund option receive a ***full*** $35 flat payment, instead of $2.04 under the original pro-ration.

3. Additional monies have been allocated to the Group B drugs, resulting in more robust payouts under the original Total Recognized Loss formulation and, in many cases, a substantial percentage of their actual damages.

Plaintiffs and Class Counsel believe that the proposal contained in this supplemental submission accomplishes the Court's goals of (i) linking the distribution methodology to actual damages and providing a premium for the Group A "Heartland Drugs," consistent with the Court's prior approval of the AstraZeneca Class 1 and BMS settlements, and (ii) providing enhanced recovery for the Group B drugs. The proposed reallocation and redistribution is supported by Class Counsel and the Class Representatives, who respectfully request that the Court approve it.

II. THE 22 BRAND NAME DRUGS IN GROUP B SHOULD REMAIN IN GROUP B

As Plaintiffs have previously explained, Class Counsel assigned drugs to the Group B drug pool because (i) most of the drugs, as multi-source, are subject to J-Code identification challenges and the median price analysis; (ii) many of the drugs are primarily administered in the inpatient hospital setting, making the level of Medicare Part B reimbursement low; (iii) many of the Group B drugs are inexpensive, resulting in a low level of Class damage; (iv) spreads on the small group of single-source branded drugs in the Group B pool tend to be small; and (v) there was a dearth of spread marketing evidence for these defendants. *See* Dkt. No. 7697.[1]

[1] As we have previously explained, the multi-factor framework for assigning each drug to Group A or Group B, among other considerations, is: (i) where data was available, whether there were egregious spreads above the 30% yardstick expected in the industry, focusing on the extent and duration of the spreads; (ii) the company's history of creating the spread, including an analysis of whether the defendant actually increased the AWP and/or list price as opposed to just increasing the spread through discounts and rebates; (iii) whether the defendant engaged in a proactive scheme to market the spread; (iv) whether the particular drug had a substantial volume of Medicare Part B reimbursements; (v) whether Defendants' actions caused a significant amount of damages to the Classes in association with the particular drug; and (vi) the drug was single source or subject to multiple J-Code identification and median analysis issues, as have befallen the multi-source drugs and multi-brand biologics. Dkt. No. 7697 at 6.

At the August 8 hearing, the Court requested that Dr. Hartman provide additional analysis for the nine brand-name drugs in Group B for which Dr. Hartman had not previously reviewed detailed spread information (although he had reviewed other information for the nine drugs and included them in his prior Declaration). Those nine drugs are Azmacort, Cefizox, Cipro IV, Depo Provera, Enbrel, Idamycin, Mithracin, Thioplex and Trelstar. The Court explained that, in its view, the most important liability factor to evaluate is the spread. Aug. 8, 2011 Hearing Tr. at 20. The Court also adopted a clear benchmark for considering whether any of the nine drugs would be eligible for Group A consideration based on a spread analysis: a drug would be considered for Group A treatment if the drug had ***spreads that are "significantly and consistently over 40 percent***." *Id.* at 56 (emphasis added).

Defendants have provided additional pricing data for these drugs, and Dr. Hartman has concluded his review. For each of the nine drugs, Dr. Hartman concludes that spreads were not "significantly and consistently over 40 percent." Supplemental Declaration of Raymond S. Hartman in Support of Track 2 Settlement Allocation (the "Supplemental Hartman Decl."), ¶ 36. In addition, Dr. Hartman has reviewed additional pricing data for the other 13 brand name drugs in Group B for which he had already reviewed spread information and augments his prior conclusions with respect to these 13. Here also, Dr. Hartman concludes that spreads were not "significantly and consistently over 40 percent." *Id.* Based on Dr. Hartman's work, augmented by the other factors that Class Counsel considered in originally classifying drugs into Groups A and B, it remains clear that all 22 brand name drugs in the Group B drug pool should remain in the Group B category.

A. The Pricing Data Consulted

In reviewing spreads for the 22 brand name drugs in Group B, Dr. Hartman has consulted a variety of data sources, where available: (i) wholesaler pricing data; (ii) manufacturer

transaction data; (iii) average manufacturer prices, or "AMPs"; and (iv) CMS average sales prices, or "ASPs." Supplemental Hartman Decl., ¶¶ 3-8.

Wholesaler transactional sales data reflect sales made by the three major wholesalers to their customers. Following the methodology that Dr. Hartman used in damages calculations for both Track 1 and Track 2, the wholesaler customers have been limited to those providers that are relevant for Medicare Part B reimbursement, such as retail pharmacies (as appropriate), physicians and clinics. Classes of trade that are excluded are governmental entities (including correctional facilities), hospitals and managed care organizations. If a given drug is known to be sold mostly through wholesalers, then wholesaler data provides a sufficiently accurate measure of spreads. But, as Dr. Hartman has previously noted (*see* Dkt. No. 7699 at 21 n.50), wholesaler data do not include rebates, if any, or direct sales from the manufacturer to the relevant classes of trade, if any. To address this concern, Dr. Hartman also examined other data sources described below. Supplemental Hartman Decl., ¶ 7.

Where available, Dr. Hartman has used manufacturer transactional data to calculate average selling prices and spreads in his Track 1 analyses and for many drugs in Track 2. This calculation uses (i) direct sales data to track sales and discounts to the relevant classes of trade that purchased directly from the manufacturer and (ii) indirect sales data to track sales and discounts to providers that purchased through a wholesaler. The analysis also includes rebate data. Where available, manufacturer data provide the best measure of ASPs and spreads. Supplemental Hartman Decl., ¶ 8.

AMP data is also an important data source. For a manufacturer's drug to be covered by the Federal Medicaid Program, it must enter into a rebate agreement with the Centers for Medicare and Medicaid Services ("CMS"). Part of this rebate agreement requires manufacturers

to submit the Average Manufacturer Price ("AMP") to CMS. This price is provided by manufacturers to CMS on a quarterly basis and is used to calculate Medicaid rebates. AMPs generally include direct and indirect sales to classes of trade such as outpatient facilities (which could include physician offices), pharmacies, independent practice associations and clinics. Therefore, it is reasonable to rely on AMP data as reflecting average sales prices that are most relevant to Dr. Hartman's review here. Supplemental Hartman Decl., ¶ 4.

It should be noted that a spread analysis based on AMPs can provide higher spreads than those based on actual ASPs. This is because it is possible that AMPs include some discounts, such as prompt pay discounts or PBM discounts, that would not be appropriate for the providers relevant here. Furthermore, studies conducted by the Office of Inspector General have shown that the CMS ASP is frequently greater than the AMP for certain J-codes. Therefore, AMPs may reveal relatively higher spreads with respect to spreads based on ASPs (either from CMS or manufacturer transactional data) for the relevant Track Two drugs. Supplemental Hartman Decl., ¶ 4. Nonetheless, Dr. Hartman has found that spreads based on AMP data are reliable for purposes of his analysis. Indeed, where he has been able to compare AMP spreads with manufacturer transactional data spreads, the two data points generally provide very similar results. *Id.* at ¶ 5.

Where available, Dr. Hartman also consulted CMS ASPs. The Medicare Modernization Act of 2003 required that, beginning on January 2005, "drugs and biologicals not paid on a cost or prospective payment basis will be paid based on 106% of the Average Sales Price (ASP)." These ASPs are a weighted average of all NDCs and drugs that belong to a given J-code for the relevant provider classes of trade, that is, the same classes of trade that are relevant here as well.

Manufacturers submit the ASP information to CMS, and the first ASPs published in the first quarter of 2005 represent data from the third quarter of 2004. Supplemental Hartman Decl., ¶ 6.

In his analysis, Dr. Hartman specifies which pricing data source was consulted for each drug. Comparing spreads from several different data sources has helped Dr. Hartman confirm his findings. ***Importantly, Dr. Hartman concludes that he has "adequate and sufficient data to determine reliable spreads for each of the brand-name Group B drugs.***" Supplemental Hartman Decl., ¶ 35 (emphasis added).

B. Spread Analyses For The Nine Brand Name Drugs Support Their Inclusion In Group B

Dr. Hartman has already reviewed the nine drugs for which he did not previously calculate spreads. *See* Declaration of Raymond S. Hartman in Support of Track 2 Settlement Allocation (Dkt. No. 7699 (redacted)) (the "Hartman Decl."). Having since obtained pricing data from Defendants for these nine drugs, Dr. Hartman has completed his review. That review demonstrates that the nine drugs are appropriately included in Group B.

I. Azmacort

Manufactured by Aventis, Azmacort is an inhalation drug that is used to prevent asthma attacks. Because Azmacort is a metered-dose inhalation product, it is typically provided via a pharmacy and not a physician's office. Consequently, there are little or no direct sales to physician offices, and wholesaler data provides a reliable source of spread information. Supplemental Hartman Decl., ¶ 10.

The quarterly wholesaler data spreads are almost all below 30%. For a very few quarters and few NDCs, spreads reach as high as 31%. Spreads based on ASPs calculated from manufacturer data are all below 30%, thus confirming the wholesaler data spreads. Spreads are

thus not "significantly and consistently over 40 percent" for Azmacort over the relevant time period. *Id.* Azmacort appropriately remains a Group B drug.

2. Cefizox

Cefizox is an injectable, third-generation cephalosporin antibiotic used to treat severe pneumonia, bone and joint infections and sepsis. It is manufactured by Fujisawa and is primarily a hospital inpatient drug with relatively little Medicare Part B utilization. AMP spreads for Cefizox tend to vary substantially by NDC. A review of AMP data spreads for Cefizox reveals some spreads above 40% for 5 out of 9 NDCs. But spreads are below 32% for some NDCs and time periods. Therefore, it cannot be concluded that spreads for Cefizox are "significantly and consistently over 40 percent." Furthermore, it should be noted that Cefizox accounts for only 24,327 administrations out of 37.6 million in the claims data (about 0.06%); the total member obligation is only about $109,000; and the average member copay obligation is only $4.50. Supplemental Hartman Decl., ¶ 11. Cefizox should remain in Group B.

3. Cipro IV

Cipro IV is an injectable antibiotic used mostly in the hospital setting and was manufactured by Bayer. An examination of manufacturer direct sales data shows that 99.7% of all sales were made through wholesalers, after excluding sales to government and hospitals. Therefore, wholesaler data are a reliable source of spread information. Quarterly wholesaler sales data spreads are almost all below 30%. Two NDCs have higher spreads, but these two NDCs account for only 2% of all wholesaler sales. Spreads are thus not "significantly and consistently over 40 percent" for Cipro IV over the relevant time period. Note also that Cipro IV accounts for only 5,772 administrations out of 37.6 million in the CMS data. Supplemental Hartman Decl., ¶ 12. Cipro IV should remain a Group B drug.

4. Depo Provera

Depo Provera, manufactured by Pharmacia, is a form of progesterone and is primarily used as a contraception to prevent pregnancy. Weighted average spreads for the Depo Provera J-code using AMP data for 1998 through 2003 are below 40%. Similarly, quarterly spreads based on wholesaler data are similar and are well below 40% across the relevant time period. The CMS ASP spread for Depo Provera in 2004 is less than 30%. Spreads are thus not "significantly and consistently over 40 percent" for Depo Provera over the relevant time period. Supplemental Hartman Decl., ¶ 13. Depo Provera belongs in Group B.

5. Enbrel

Enbrel is used to treat arthritis and is manufactured by Amgen. The quarterly wholesaler data spreads are all below 30%. Similarly, the quarterly AMP data spreads are very close to the wholesaler data spreads and are also all below 30%. Finally, the 2004 spread based on CMS ASPs is also below 30%. Dr. Hartman does not find spreads that are "significantly and consistently over 40 percent" for Enbrel over the relevant time period. Supplemental Hartman Decl., ¶ 14. Enbrel remains a Group B drug.

6. Idamycin

Idamycin is a chemotherapy drug manufactured by Pharmacia. Quarterly wholesaler data spreads are almost all below 30%, with only a few quarters reaching as high as 36%. Quarterly AMP data spreads are very close to wholesaler data spreads, though one out of the four NDCs has spreads that reach above 40% in 2004. However, Idamycin went generic in 2003. Therefore, the slightly higher spreads in 2004 are irrelevant. Spreads are not "significantly and consistently over 40 percent" for Idamycin over the relevant time period. Note also that Idamycin accounts for only 2,068 transactions out of 37.6 million in the CMS data. Supplemental Hartman Decl., ¶ 15. Idamycin should remain in Group B.

7. Mithracin

Mithracin is an antineoplastic cancer medication used to treat certain types of testicular cancer and is manufactured by Bayer. According to a Senior Vice President at Bayer, the company has not maintained a sales force for Mithracin for at least the last 20 years, and Bayer discontinued the drug in 2001. Quarterly AMP data spreads are all below 30%. The same is true of spreads calculated from 2004 CMS ASPs. Therefore, spreads are not "significantly and consistently over 40 percent" for Mithracin over the relevant time period. Supplemental Hartman Decl., ¶ 16. Mithracin is appropriately classified in Group B.

8. Thioplex

Manufactured by Immunex, Thioplex is used in chemotherapy for bladder, ovarian, breast and lung cancers. Thioplex faced generic competition starting in 2001. Quarterly wholesaler data spreads are virtually all below 30%. Annual AMP spreads are similar, ranging from 30% to 35%. Spreads are not "significantly and consistently over 40 percent" for Thioplex over the relevant time period. Supplemental Hartman Decl., ¶ 17. Thioplex should remain a Group B drug.

9. Trelstar

Trelstar is a drug used to treat prostate cancer and is manufactured by Pharmacia. It competes with drugs like Eligard, Lupron and Zoladex, though its share of this market is extremely small. Furthermore, Pharmacia did not market Trelstar to physicians or other providers and instead sold 99% of the product through wholesalers. Consequently, wholesaler data are a reliable source of spread information. The quarterly wholesaler data spreads for Trelstar are all below 30%. Spreads thus are not "significantly and consistently over 40 percent" for Trelstar over the relevant time period. Supplemental Hartman Decl., ¶ 18. Trelstar should remain a Group B drug.

C. Additional Pricing Data For The Remaining 13 Brand Name Drugs Supports Their Inclusion In Group B

For each of the remaining 13 brand name drugs in Group B, Dr. Hartman had already reviewed spreads based on pricing data and reported the results in his August 3, 2011 Declaration. With that pricing data now supplemented (usually by the addition of AMP data), Dr. Hartman augments his opinions as follows.

1. AccuNeb

AccuNeb, made by Dey, is an albuterol sulfate solution used in nebulizers to treat acute asthma attacks and COPD. Although AccuNeb is a brand name drug with a particular dosage that did not have AB-rated generic competitors during the relevant time period, it shares a J-code with generic albuterol sulfate. Therefore, it is subject to the median price analysis. In any event, an analysis of manufacturer transaction data ASPs shows spreads that are below 30% for the relevant classes of trade during the relevant time period. In addition, quarterly wholesaler data spreads are all less than 30%. Spreads are not "significantly and consistently over 40 percent" for AccuNeb over the relevant time period. Supplemental Hartman Decl., ¶ 20. AccuNeb should stay in Group B.

2. Aromasin

Aromasin is a chemotherapy drug used to treat cancers such as lymphomas and testicular cancers. It is a tablet form drug manufactured by Pharmacia. Although this is a self-administered drug, it is covered by Medicare Part B because it is used in chemotherapy. Because Aromasin is in tablet form, it is typically dispensed though retail pharmacies and generally not sold directly to physicians. As such, wholesaler data is an appropriate source for spread information. Quarterly wholesaler data spreads are all below 30%. Spreads are thus not

"significantly and consistently over 40 percent" for Aromasin over the relevant time period. Supplemental Hartman Decl., ¶ 21. Aromasin is appropriately classified in Group B.

3. Calcijex

Calcijex is an injection of the active form of Vitamin D and is used to treat low calcium due to dialysis or hypoparathyroidism. It is manufactured by Abbott. Calcijex faced generic competition starting in 2001. Therefore, starting in 2001, it is subject to the median price analysis discussed in Dr. Hartman's August 5, 2011 Declaration. Quarterly spreads based on wholesaler data are almost all less than 30%, with only one NDC-quarter reaching as high as 31%. Quarterly spreads based on AMPs are similar and range from about 27% to 36%. Spreads are not "significantly and consistently over 40 percent" for Calcijex over the relevant time period. Supplemental Hartman Decl., ¶ 22. Calcijex should remain in Group B.

4. Calcimar

Calcimar, manufactured by Aventis, is used to treat osteoporosis and Paget's disease of the bone. Its molecule name is "calcitonin, salmon," and, as of the 1998 edition of the Red Book, there were at least two other generic competitors for this molecule name. Therefore, this is a multi-source drug and is subject to the median price analysis. Spread information is unavailable for this drug, but given that it was a multi-source drug in 1998 and discontinued in 1999, this is of little consequence. Calcimar should not have been classified as a Group B brand-name drug but, nonetheless, appropriately remains in Group B as a multi-source drug. Supplemental Hartman Decl., ¶ 23.

5. Camptosar

Camptosar is a chemotherapy drug usually given in combination with other drugs to treat cancers of the colon and rectum. It is manufactured by Pharmacia. Wholesaler data spreads are typically between 25% and 35%. Spreads based on quarterly AMP data are approximately the

same, ranging from about 28% to 38%. Spreads are thus not "significantly and consistently over 40 percent" for Camptosar over the relevant time period. Supplemental Hartman Decl., ¶ 24. Camptosar should remain in Group B.

6. Eligard

Eligard is used to treat prostate cancer and is manufactured by Aventis. It launched in May 2002 and competes with Lupron and Zoladex. In fact, Eligard's only J-code is also shared with Lupron, thus making it impossible from the CMS data to determine if a CMS claim for this J-code is for Lupron or Eligard after Eligard's introduction in May 2002. Furthermore, Aventis documents show that Eligard accounted for a very small dollar-based market share of only 1.9% at the beginning of 2003, a 4.4% annual average for 2003, and 7.9% as of March 2004 (as compared to Lupron and Zoladex). Supplemental Hartman Decl., ¶ 25.[2]

Weighted average AMP data spreads for Eligard are almost all below 30% and are always below 40%. Quarterly wholesaler data spreads are very similar to the AMP spreads, with almost all quarters having spreads below 30% and just a few quarters and NDCs with spreads between 30% and 40%. No wholesaler data spreads are above 40%. Dr. Hartman thus does not find spreads that are "significantly and consistently over 40%" for Eligard over the relevant time period. Supplemental Hartman Decl., ¶ 26. Eligard is appropriately classified as a Group B drug.

Review of the CMS data also reveals that most claims under the common Eligard/Lupron J-Code are for Lupron and not Eligard. Approximately 50% of the co-pay obligations for the Eligard/Lupron J-Code were incurred ***before*** Eligard was even introduced to the market in May

[2] As these market share statistics reveal, Eligard was not well received by physicians when it was introduced. Eligard was first brought to market in 1-month and then 3-month formulations that proved to be less popular than its 6-month formulation, which was not introduced until after the class period in 2005. In addition, Eligard – unlike Lupron – required refrigeration, which many providers apparently found inconvenient.

2002. This means that these were actually claims for Lupron given the shared J-code. Based on Eligard's introduction during the second quarter of 2002 and its estimated market shares described above, Dr. Hartman estimates that no more than 2.4% of the total co-pay obligations appearing in the CMS data are truly Eligard administrations (and not Lupron administrations). Supplemental Hartman Decl., ¶ 27. This evidence supports requiring class members claiming to have been administered Eligard to prove with supporting documentation that they were, in fact, administered Eligard and not Lupron. As discussed below in Section III, this will substantially reduce the total outlay for Eligard and thereby increase the payments to all Group B drug claimants, including those who can prove they were administered Eligard.[3]

7. Ellence

Ellence, manufactured by Pfizer, is used to treat certain kinds of breast cancer after surgery. Quarterly spreads based on wholesaler data are almost all below 30%. Only a handful of quarters reach above 30% and they never exceed 40%. AMP spreads are very similar to the wholesaler data spreads, with only a few quarters reaching barely above 30%. Spreads based on CMS ASP data are also below 30%. Spreads are not "significantly and consistently over 40 percent" for Ellence over the relevant time period. Supplemental Hartman Decl., ¶ 28. Ellence should remain in Group B.

8. Leukine

Leukine is a bone marrow stimulator that is used to treat leukopenia (low white blood cell count). It was manufactured by Immunex, although Immunex divested the drug and stopped

[3] As the Court is aware, objector Haviland has focused intently on Eligard, although he never had an expert calculate spreads. The Court should also be aware that, in the Commonwealth of Pennsylvania case that Haviland is fond of citing, Pennsylvania did ***not*** target Eligard in its last operative complaint, which was filed in 2005. *See* Declaration of Steve W. Berman in Support of Plaintiffs' Second Supplemental Submission In Support of Rebalanced Track Two Settlement ("Supplemental Berman Decl."), Ex. A (*see* paragraph 45 identifying the Aventis drugs and paragraphs 734-87 containing the Aventis allegations). Even so, this did not prevent Pennsylvania from including all Aventis drugs in the settlement release. *See id.* Ex. B at page 3, ¶ E (defining drugs subject to the Agreement as all drugs manufactured by Aventis).

manufacturing it in 2002. Quarterly spreads based on wholesaler data are almost all below 30%, with a few quarters having spreads of about 31%. Spreads based on quarterly AMP data range from 32% to 38%. The spread based on 2004 CMS ASP data is about 41%, but note that this occurs ***after*** Immunex sold the drug. Dr. Hartman finds that spreads are not "significantly and consistently over 40 percent" for Leukine over the relevant time period. Supplemental Hartman Decl., ¶ 29. Leukine should remain in Group B.

9. Lovenox

Lovenox is used as a blood thinner to prevent blood clots and is manufactured by Aventis. Manufacturer data spreads are almost all below 30% and never reach above 40%. Spreads based on quarterly wholesaler data are very similar, again with most spreads below 30% and no spreads above 40%. The 2004 spread based on CMS ASP data is about 32%. Lovenox does not have spreads that are "significantly and consistently over 40 percent" over the relevant time period. Supplemental Hartman Decl., ¶ 30. Lovenox should stay in Group B.

10. Novantrone

Novantrone is used to treat Multiple Sclerosis and is sometimes used to treat prostate cancer and leukemia. It is manufactured by Immunex. Spreads based on manufacturer data are well below 40% in almost all years, except in 1999 where the spreads reached about 44%. AMP data spreads are comparable to the manufacturer data spreads. Spreads based on wholesaler data are very close to the manufacturer data spreads as well, with most below 30% and a limited number as high as 42%. Though some spreads in the data are at or above 40%, there is no enduring pattern and spreads are mostly below 40% over time. Thus, Dr. Hartman does not find that spreads that are "significantly and consistently over 40 percent" for Novantrone over the relevant time period. Supplemental Hartman Decl., ¶ 31. Novantrone should remain in Group B.

11. Prograf

Prograf, manufactured by Immunex, is an immunosuppressant used to treat patients with organ transplants. Manufacturer data spreads are less than 30% for all years from 1998 through 2003. Quarterly spreads based on wholesaler data are all below 30%. The CMS ASP data spread for 2004 is 37%. Spreads are not "significantly and consistently over 40 percent" for Prograf over the relevant time period. Supplemental Hartman Decl., ¶ 32. Prograf is appropriately categorized in Group B.

12. Taxotere

Taxotere is used to treat breast cancer and is manufactured by Aventis. In Table 3 of the August 5, 2011 Hartman Declaration, Dr. Hartman already summarized spreads for Taxotere, finding that manufacturer data spreads range from 29% to 35%. Spreads based on wholesaler data are very similar to the manufacturer data spreads. Finally, the 2004 CMS ASP spread is 25%. Spreads are not "significantly and consistently over 40 percent" for Taxotere over the relevant time period. Supplemental Hartman Decl., ¶ 33. Taxotere should remain in Group B.

13. Zemplar

Zemplar, manufactured by Abbott, is a man-made form of Vitamin D that is used to treat secondary hyperparathyroidism (over activity of the parathyroid gland) in patients with chronic kidney failure. Spreads calculated using manufacturer data range from 25% to 38%. Quarterly spreads based on wholesaler data are very similar to the manufacturer data spreads, where almost all are less than 30%, and spreads never reach 40%. Spreads are not "significantly and consistently over 40 percent" for Zemplar over the relevant time period. Supplemental Hartman Decl., ¶ 34. Zemplar should stay in Group B.

III. ADDITIONAL CHANGES TO THE REALLOCATION AND REDISTRIBUTION PLAN

Based on the Court's comments at the hearing, Plaintiffs propose two additional changes to the distribution plan. First, Epogen will now be a Group B drug, and claimants will have to demonstrate that they were administered Epogen and not Procrit for non-dialysis use. *See* Aug. 8, 2011 Hearing Tr. at 44-53. Second, Group A overcharges will be doubled only for the Heartland Period ending December 31, 2003.[4]

Plaintiffs propose a third change based on Dr. Hartman's additional analysis of Eligard data as described above in Section II.C.6. Because Eligard shares a J-Code with Lupron, and because Dr. Hartman has estimated that 97.6% of the administrations in the CMS data for that J-Code are for Lupron and not Eligard, class members claiming to have been administered Eligard must prove with supporting documentation that they were, in fact, administered Eligard and not Lupron.

The projected impact of the foregoing changes is reported in the Second Supplemental Declaration of Daniel Coggeshall Regarding Estimated Net Consumer Settlement Fund and Estimated Class 1 and Class 3 Consumer Payments for the Track Two Settlement (the "Second Supplemental Coggeshall Decl.").[5] We have assumed that no more than $105,000 in total co-pays will each be claimed for the drugs Epogen and Eligard, respectively. As, Exhibit B to the Second Supplemental Coggeshall Declaration shows, the estimated pro rata co-pay recovery for

[4] This change only impacts Class 3, because eligible Class 1 administrations already ended in 2003.

[5] During the August 8 hearing, Class Counsel suggested moving Neupogen from Group A to Group B given that Dr. Hartman had calculated only $359,047 in Class damage for Neupogen. Aug. 8, 2011 Hearing Tr. at 67. Upon further analysis, we believe that Neupogen should remain a Group A drug. Moving it to Group B and, thereby, basing recovery on co-pays and not actual damages would actually ***increase*** the payout for Neupogen and adversely impact the payouts for the other Group B drugs, reducing the estimated pro rata by 1.3%. It is, therefore, more sensible to continue to tie Neupogen's recovery to actual damages and keep the drug in Group A. ***And as this exercise demonstrated, inclusion of a drug in Group B does not necessarily result in reduced compensation vis-à-vis Group A.***

the Group B drugs is now just under 15 percent. This represents a 255% increase over the 5.868% estimated pro rata recovery associated with the original redistribution formula. *See* Dkt. No. 7648.[6]

And it is important to continue emphasizing that Group B claimants are projected to recover 15% of their co-pay, which itself is much greater than actual damage (which is but a percentage of the co-pay). Further, many of the Group B drug administrations will be credited a substantial portion of damages in this settlement. For example, claimants taking Eligard will on average receive approximately $39.53 per $263.56 average co-pay transaction for a drug for which Dr. Hartman finds no damages. Similarly, for Trelstar, another drug for which Dr. Hartman finds zero damages, claimants will receive on average approximately $19.71 per $131.37 average co-pay transaction. For Gamimune, a multi-brand biologic subject to the median analysis, claimants will receive $49.44 per $329.58 average co-pay transaction.[7] Multiplied by numerous administrations, these per-copay recoveries add up to significant checks going to these claimants.

In sum, the modified reallocation and redistribution plan, as it presently stands, accomplishes the following:

1. Class 1 and 3 consumers receive ***double*** their actual damages incurred on eligible administrations of Group A drugs for administrations during the Court's "Heartland Period."

2. Class 3 consumers electing the "Easy Pay" refund option receive a ***full*** $35 flat payment, instead of $2.04 under the original pro-ration.

---

[6] Note that in Exhibit B the Class 1 payouts for the Group A drugs have increased. This is because Rust is continuing to adjudicate claims and update the database; it is not the result of any changes to the distribution methodology.

[7] The average co-pay per transaction for these drugs is taken from Table 3 to the Hartman Declaration filed on August 3, 2011 (Dkt. No. 7699). We have calculated the amount that each claimant will receive per average co-pay transaction by simply multiplying the average co-pay per transaction by 15%, which is the estimated pro rata recovery projected for Group B drugs.

3. Additional monies have been allocated to the Group B drugs, resulting in more robust payouts under the original Total Recognized Loss formulation and, in many cases, a substantial percentage of their actual damages.

Thus, under this proposal, ***all*** Class 1 and Class 3 consumers will receive more than their actual damages for their Group A drug administrations and will receive a substantial amount for Group B drug administrations. The Class 1 and Class 3 splits would be as follows:

- Class 1 will receive a total of approximately **$14,853,407.27** – $6,648,704.58 for Group A drugs and $8,204,702.69 for Group B drugs. *See* Second Supplemental Coggeshall Decl., Ex. B.

- Class 3 will receive a total of approximately **$1,707,681.10** – $249,251.60 for Group A drugs, $1,005,888.25 for Group B drugs, and $452,541.25 total in $35 Easy Pays. *See* Second Supplemental Coggeshall Decl., Ex. B.

The splits by drug groupings would be as follows: Group A, $6,897,956.18; Group B, $9,210,590.94; $452,541.25 in $35 Easy Pay flat payments. The $9,210,590.94 for the Group B drugs is 2.3 times more than the $4,030,393.02 previously allocated to the Group B drugs in Plaintiffs' July 5, 2011 redistribution proposal (*see* Dkt. No. 7648, Ex. D).

IV. EVIDENTIARY SUBMISSION REGARDING CLASS 3 CLAIMS DEADLINES ON THE SETTLEMENT WEBSITE

As Plaintiffs previously reported to the Court, there was a minor error on the settlement website with respect to the Class 3 claims deadline. *See* Dkt. No. 7647 at 10-11. In sum, long after the February 1, 2010 deadline had passed, an incorrect Class 3 claims deadline was added to the website after the Court issued its February 9, 2011 order revising the schedule for Class 1 but not Class 3 claims. Obviously, since the Class 3 claims deadline ***had already passed***, this error – which has been remedied – is of no consequence and could not possibly have discouraged Class 3 claims – highlighting the frivolity of the Landrigan objection. The Court has requested an evidentiary declaration from Rust, which we are filing herewith. *See* Declaration of Daniel

Coggeshall Regarding the Class 3 Claims Deadline on the Website for the Track Two Settlement.

V. BCBSMA'S STATUS AS AN ISHP

At the August 8, 2011 hearing, the Court requested clarification concerning the status of Independent Settling Health Plans ("ISHPs") in the Settlement. August 8, 2011 Hearing Tr. at 118-22. As explained during the hearing, consistent with each of the AWP settlements and other drug settlements involving an ISHP group, the ISHPs are defined out of the proposed settlement classes. In other words, the classes are defined to exclude ISHPs such that no formal request for exclusion is necessary.

After setting forth the definition of each of Classes 1, 2 and 3, the Agreement delineates entities excluded from the proposed settlement Classes (such as Defendants, successors and assigns etc.) and then provides:

> Additionally excluded from each of the Settlement Classes are the following: (1) all natural persons who only paid flat co-payments, and not any percentage co-payments, for Class Drugs; (2) all federal, state, and local governmental entities in the United States, except any such governmental agencies or programs that made or incurred an obligation to make a reimbursement for a Class Drug as part of a health benefit plan for their employees, but only with respect to such payments; and (3) ***the ISHPs***.

Agreement, p. 6 (emphasis added). This is consistent with the way the settlement classes were defined in each of the previous AWP settlements that have included an ISHP group. Both the GSK Settlement and the AstraZeneca Class 2 and 3 Non-Massachusetts Settlement also excluded ISHPs from the settlement classes by definition. *See* GSK Settlement Agreement (Dkt. No. 2971) p. 7; AZ Class 2 and 3 Settlement Agreement (Dkt. No. 7143) p. 6.[8]

[8] The remaining AWP settlements, namely the AstraZeneca Class 1 Settlement, the AstraZeneca Class 2 and 3 Massachusetts Settlement and the BMS Settlement, did not include participation by ISHPs. The AstraZeneca Class

While excluding ISHPs from the class definition accomplishes the same function as a request for exclusion, ISHPs are not part of the settlement classes. Thus, there is a fundamental distinction between TPPs who file a request for exclusion and TPPs who participate as ISHPs. As part of the Settlement, ISHPs agreed to resolve their claims with Defendants rather than retain the right to pursue those claims separate from the Class. ISHPs have agreed to settle their claims on the same basis as the Class and accept the share of settlement proceeds allocated to TPPs that ISHPs would have otherwise been entitled if they participated as members of the Class. ISHPs bear the same costs of litigation, attorney fees, and costs of notice and administration related to the Settlement as TPP Class Members. The only difference in how ISHPs are treated involves an initial payment of a portion of the settlement funds in exchange for an immediate release of their claims. ISHPs provide this release at the time they are provided the initial payment and the release is effective irrespective of whether the Court approves the Settlement.

Shortly after preliminary approval of the Settlement, ISHPs were provided an initial payment of $25.5 million. The remaining funds available to pay ISHPs are subject to a "true-up" between the ISHPs and TPP Class Members. In exchange for the initial payment, ISHPs fully release their claims. Because they are separately represented and are not class members, ISHPs can provide a release without need for Court approval or the time involved in providing notice. In return, the Agreement provides for an expedited payment of some portion of the monies ISHPs would ultimately be entitled to in the Settlement.

The true-up formula is a simple one. Each TPP Class Member and ISHP claim is calculated in exactly the same manner – as a percentage of all combined TPP and ISHP claims. The amount of funds paid to the ISHPs after all claims have been calculated by the Claims

1 Settlement only involved Medicare consumers, not TPPs. In the BMS Settlement and the AstraZeneca Class 2 and Class 3 Massachusetts Settlement, ISHPs filed claims and participated in the settlement as TPP Class Members.

Administrator will account for the $25.5 million initial payment. Essentially, the $25.5 million will be subtracted from what ISHPs are ultimately entitled to and they will be paid the balance at the end of the claims and auditing process.

At the August 8, 2011 hearing, the Court also inquired about the specific status of Blue Cross Blue Shield of Massachusetts in the Settlement. Aug. 8, 2011 Hearing Tr. at 122 ("[a]nd BCBS, was it part of the group that you understood right from the get-go was an independent settling health plan no matter whether you describe it as an opt-out or as a definition?"). The simple answer to the Court's question is "yes." While BCBSMA participated in the litigation of Track One claims and in the Massachusetts Track One trial, BCBSMA made it clear to Class Counsel that they would not participate in the same manner concerning claims against Track Two Defendants. Class Counsel understood that BCBSMA would participate as an ISHP in this Settlement before a settlement was reached, and BCBSMA appeared on the list of ISHP members when the list was first presented to the Court for preliminary approval. *See* Dkt. No. 5408.

VI. APPEALING OBJECTORS SHOULD BE REQUIRED TO POST AN APPEAL BOND

At the August 8, 2011 fairness hearing, the Court requested briefing on whether it would be appropriate to impose an appeal bond if an objector appeals the Track Two Settlement after final approval. Aug 8, 2011 Hearing Tr. at 135-36. Under Rule 7 of the Federal Rules of Appellate Procedure, the Court "may require an appellant to file a bond or provide other security in any form and amount necessary to ensure payment of costs on appeal." Earlier in this litigation, the Court imposed an appeal bond when an objector appealed the GlaxoSmithKline nationwide settlement. *See In re Pharm. Indus. Average Wholesale Price Litig.*, 520 F. Supp. 2d 274 (D. Mass. 2007).

In the GSK case, the Court recognized that in the class action settlement context, "costs under Rule 7 may also include administrative costs to the classes that will likely be caused by the delay." *Id.* at 277 (citing *Barnes v. FleetBoston Fin. Corp.*, 2006 U.S. Dist. LEXIS 71072, at *8-9 (D. Mass. Aug. 22, 2006); *In re Compact Disc. Minimum Advertised Price Antitrust Litig.*, 2003 WL 22417252 (D. Me. Oct. 7, 2003); *In re NASDAQ Mkt.-Makers Antitrust Litig.*, 187 F.R.D. 124, 128-129 (S.D.N.Y. 1999)). The Court therefore imposed an appeal bond that included administrative costs.

Furthermore, if the Court determines that an objector's appeal is frivolous, the Court can also include attorneys' fees in an appeal bond. "The First Circuit has held that when the district court determines that an appeal may be frivolous, it may require security for the costs, including appellate attorneys' fees . . ." *In re Pharm. Indus. Average Wholesale Price Litig.*, 520 F. Supp. 2d at 277 (citing *Sckolnick v. Harlow*, 820 F.2d 13, 15 (1st Cir. 1987)). The First Circuit continues to support the inclusion of attorneys' fees where appeals bear "the indicia of frivolousness" and in other appropriate circumstances, such as where an appellee would be eligible to recover attorneys' fees under a statutory fee-shifting provision. *Int'l Floor Crafts, Inc. v. Dziemit*, ___ F.3d ___, 2011 WL 1519113, at *9-10 (1st Cir. Apr. 21, 2011).

If the Court grants final approval and an objector appeal ensues, it will be appropriate to impose an appeal bond. Class Counsel will move for the imposition of such a bond at that time and will ask for all appropriate security including the payment of the substantial attorneys' fees that will be incurred by Plaintiffs in responding to the appeals. We will vigorously pursue these costs from the objectors.

DATED: August 19, 2011

By **/s/ Steve W. Berman**

Thomas M. Sobol (BBO#471770)
Edward Notargiacomo (BBO#567636)
Hagens Berman Sobol Shapiro LLP
One Main Street, 4th Floor
Cambridge, MA 02142
Telephone: (617) 482-3700
Facsimile: (617) 482-3003

Steve W. Berman
Sean R. Matt
Hagens Berman Sobol Shapiro LLP
1918 Eighth Avenue, Suite 3300
Seattle, WA 98101
Telephone: (206) 623-7292
Facsimile: (206) 623-0594

Jennifer Fountain Connolly
Hagens Berman Sobol Shapiro LLP
1629 K St. NW, Suite 300
Washington, D.C. 20006
Telephone: (202) 355-6435
Facsimile: (202) 355-6455

Jeffrey Kodroff
John A. Macoretta
Spector, Roseman, Kodroff & Willis, P.C.
1818 Market Street, Suite 2500
Philadelphia, PA 19103
Telephone: (215) 496-0300
Facsimile: (215) 496-6611

Kenneth A. Wexler
Wexler Wallace LLP
55 W. Monroe Street, Suite 3300
Chicago, IL 60603
Telephone: (312) 346-2222
Facsimile: (312) 346-0022

Marc H. Edelson
Hoffman & Edelson LLC
45 West Court Street
Doylestown, PA 18901
Telephone: (215) 230-8043
Facsimile: (215) 230-8735
Co-Lead Counsel

CERTIFICATE OF SERVICE BY LEXISNEXIS FILE & SERVE

Docket No. MDL 1456

I, Steve W. Berman, hereby certify that I am one of plaintiffs' attorneys and that, on August 19, 2011, I caused copies of ***Plaintiffs' Second Supplemental Submission in Support of a Rebalanced Track Two Settlement***, to be served on all counsel of record by causing same to be posted electronically via Lexis-Nexis File & Serve.

/s/ Steve W. Berman
Steve W. Berman